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10/591,864	12/05/2006	Claire Mallard	129329	3442
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Oliff & Berridge, PLC			SCHLENTZ, NATHAN W	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/591,864

**Applicant(s)**

MALLARD ET AL.

**Examiner**

Nathan W. Schlientz

**Art Unit**

1616

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33, 35-47, 50-55, 57-60, 62 and 64-78 is/are pending in the application.
- 4a) Of the above claim(s) 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33, 35-47, 50-55, 57-60, 62 and 65-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ ~~Copies of the certified copies of the priority documents have been received in this National Stage~~  
application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 33, 35-47, 50-55, 57-60, 62 and 64-78 are pending in the present application. Claim 64 is withdrawn as being drawn to nonelected subject matter. Therefore, claims 33, 35-47, 50-55, 57-60, 62 and 65-78 are examined herein on the merits for patentability. No claim is allowed at this time.

### ***Election/Restrictions***

2. Claim 64 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 25. The traversal is on the grounds that the common technical features distinguish over the applied prior art. This is not found persuasive because, as discussed below, Schulz et al. (US 5,654,362) discloses the common technical features.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon allowance of the product claims, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### ***Withdrawn Rejections***

3. Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

***Claim Rejections - 35 USC § 112, Fourth Paragraph***

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

4. Claim 39 is rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claim 39 recites "wherein [the composition as claimed in claim 33] comprises *at least one silicone agent, a hydrocarbon-based compound*, an active ingredient in a solubilized form, and an alcohol-type solvent". The recitation of "at least one silicone agent" and "a hydrocarbon-based compound" are broader than the limitations of claim 33. The only limitation in claim 39 that further limits claim 33 is the recitation of an alcohol-type solvent. Applicant may cancel the claim, amend the claim to place the claim in proper dependent form, rewrite the claim in independent form, or present a sufficient showing that the dependent claim complies with the statutory requirements.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 33, 35-39, 42, 45-47, 50, 52-55, 57, 59, 60, 62, 65-67, 70, 74, 75 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulz et al. (US 5,654,362).

Schulz et al. disclose preparation of a silicone powder by combining an organopolysiloxane (average structure  $\text{Me}_3\text{SiO}(\text{Me}_2\text{SiO})_{108}(\text{MeHSiO})_{10}\text{SiMe}_3$ ), 1,13-tetradecadiene, octamethylcyclotetrasiloxane, and platinum divinyl tetramethyl disiloxane complex catalyst (Karstedt's catalyst) followed by mechanical stirring to break the mixture into a powder (Example III). Schulz et al. then add 70 parts of this powder to 6 parts of octyl palmitate (emollient and thickening agent), 23 parts of an antiperspirant active and 1 part of fragrance (Table I). Schulz et al. disclose that the emollient can also comprise lanolin wax, and the composition is also useful as delivery systems for oil and water soluble substances such as vitamins (col. 7, ln. 27 and 57-58). Schulz et al. further disclose that other types of solvents can swell the silicone elastomer, such as alcohols and fragrances (col. 4, ln. 55 to col. 5, ln. 53). Carrying out the invention is simply a matter of combining the polysiloxane, the alpha, omega-diene, the low molecular weight silicone oil or other solvent, and the catalyst; and mixing these ingredients at room temperature until a gel is formed (col. 5, ln. 54-59). Therefore, Schulz et al. clearly envisaged compositions comprising an active ingredient, such as oil and water soluble substances such as vitamins, and pharmaceuticals, combined with a silicone agent and a thickening agent. See also claims 1-18.

***Response to Arguments***

Applicant argues on page 10 that Schulz is directed to methods of thickening silicone oils or other solvents to gel-like consistency. Applicant further states that, as acknowledged by the Office Action on page 15, Schulz is silent regarding a composition "comprising at least one agent for promoting the penetration of the active ingredient into the skin," as recited in claim 33. Furthermore, Schulz fails to teach "a thickening agent different from the silicone agent ... said thickening agent being a hydrocarbon-based wax of animal, plant, mineral or synthetic origin, or a mixture thereof," as recited in claim 33. Thus, for at least these reasons, Schulz fails to disclose each and every limitation of claim 33.

First, the examiner respectfully argues that pg. 15 of the Office action mailed 28 October 2010 does not state that Schulz et al. is silent regarding a composition "comprising at least one agent for promoting the penetration of the active ingredient into the skin". On the contrary, Schulz et al. clearly disclose that glycols and glycol ethers, such as ethylene glycol, propylene glycol, glycerol, ethylene glycol monomethyl ether, ethylene glycol monomethyl ether acetate, diethylene glycol monobutyl ether, and propylene glycol monophenyl ether, can be included in the compositions of their invention (col. 5, ln. 1-5 and 14-17). The Office action stated that Schulz et al. do not explicitly disclose ***the amount of... agent for promoting the penetration of the active ingredient into the skin***, as recited in instant claims 58 and 76.

Second, the examiner respectfully argues that Schulz et al. do disclose a thickening agent different from the silicone agent... said thickening agent being a hydrocarbon-based wax of animal, plant, mineral or synthetic origin, or a mixture

thereof. Instant claim 50 states that the hydrocarbon-based wax is selected from the group consisting of glyceryl esters and esters of saturated and unsaturated fatty acids having from 10 to 24 carbon atoms. Schulz et al. included octyl palmitate, an ester of a saturated fatty acid having 24 carbon atoms, into their compositions (Table 1), and further states that emollients other than octyl palmitate can be used in the formulation, including fatty acid esters, such as isopropyl myristate, isopropyl palmitate, isopropyl stearate, butyl stearate, cetyl stearate, diisopropyl adipate, isodecyl oleate, diisopropyl sebacate and lauryl lactate, and lanolin wax (col. 7, ln. 13-14 and 18-21 and 26).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.



6. Claims 33, 35-47, 50-55, 57-60, 62 and 65-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulz et al. (US 5,654,362) in view of Sakuta (US 6,503,519).

*Determination of the scope and content of the prior art*

*(MPEP 2141.01)*

The teachings of Schulz et al. are discussed above and incorporated herein by reference.

*Ascertainment of the difference between the prior art and the claims*

*(MPEP 2141.02)*

Schulz et al. do not explicitly disclose the vitamins that can be carried by their invention to comprise vitamin D. However, one of ordinary skill in the art would readily choose vitamin D from the list of vitamins suitable for administration because it is a known vitamin and because Sakuta teaches vitamin D as suitably carried by silicone compositions for cosmetic application (col. 5, ln. 38-43).

Sakuta teaches dermatic cosmetic material containing a silicone composition paste comprising a cross-linked silicone polymer having hydrophilic polyoxyalkylene groups (i.e. thickener) and a silicone oil, thereby enabling stable incorporation of an antiperspirant or water-soluble vitamins and further ensuring improvements in usability (Abstract). Sakuta teaches examples of compositions comprising silicone compositions prepared by mixing  $\text{Me}_3\text{SiO}(\text{Me}_2\text{SiO})_{27}(\text{MeHSiO})_2\text{SiMe}_3$  with ethanol,  $\text{CH}_2=\text{CHCH}_2(\text{C}_2\text{H}_4\text{O})_{10}\text{CH}_2\text{CH}=\text{CH}_2$ , and a 3 wt.% ethanol solution of chloroplatinic acid, then removing the solvent; followed by 100 parts by weight of the polymer being mixed

with 300 parts by weight of dimethylpolysiloxane having a viscosity of 6 mm<sup>2</sup>/s at 25 °C (Silicone Composition No. 1), and 100 parts by weight of the polymer being mixed with 400 parts by weight of decamethylcyclopentasiloxane (Silicone Composition No. 2) (Example 1). The Silicone Composition Nos. 1 and 2 are mixed with decamethylcyclopentasiloxane, dimethylpolysiloxane, dipropylene glycol, 1,3-butylene glycol, cetyl alcohol, and vitamins C and E (Examples 10-12).

Sakuta teaches that the silicone composition paste is employed as a substrate and can be combined with lower alcohols, such as ethanol and propanol (col. 3, ln. 63 to col. 4, ln. 3) and silicone oils (col. 4, ln. 4-11). The lower alcohol is preferably present from 100 to 1,000 parts by weight per 100 parts by weight of the silicone composition paste, the silicone oil is present from 100 to 1,000 parts by weight per 100 parts by weight of the silicone composition paste, and the vitamin is present from 0.5 to 100 parts by weight per 100 parts by weight of silicone composition paste (col. 5, ln. 13-37). Sakuta also teaches that the composition may comprise perfumes and vitamins including vitamin A, B, D, E, F, K, L, T and U (col. 5, ln. 38-43), and specifically teaches vitamins C and E present at a combined 2 or 3 wt.% (Examples 10-12).

Schulz et al. also do not explicitly disclose the amount of active agent, solvent, silicone elastomer, and agent for promoting the penetration of the active ingredient into the skin, as instantly claimed. However, one of ordinary skill in the art would readily be able to determine the necessary amounts of these components to be suitable for carrying active ingredients for topical administration.

Schulz et al. also do not explicitly disclose the use of glyceryl behenate or glyceryl dipalmitostearate in their silicone gels. However, it was well-known at the time of the instant invention that glyceryl behenate is a suitable emollient/skin conditioning agent for use in cosmetic formulations. Therefore, one of ordinary skill in the art would have been motivated to use it as an emollient in the topical formulations taught by Schulz et al.

*Finding of prima facie obviousness*

*Rational and Motivation (MPEP 2142-43)*

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to prepare the compositions according to Schulz et al. wherein the active agent is vitamin D, and the amounts of each component is within the scope of the instant claims. One of ordinary skill in the art at the time of the instant invention would have been able to determine the amounts of each component so that the composition acts as a suitable carrier for topical application.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Claims 33-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (US 5,929,164) in view of Sakuta (US 6,503,519) and Schulz et al. (US 5,654,362).

*Determination of the scope and content of the prior art*  
*(MPEP 2141.01)*

Zhang teaches preparation of a silicone gel by combining an organopolysiloxane (average structure  $\text{Me}_3\text{SiO}(\text{Me}_2\text{SiO})_{93}(\text{MeHSiO})_6\text{SiMe}_3$ ), 1,5-hexadiene, decamethylcyclopentasiloxane, platinum divinyl tetramethyl disiloxane complex catalyst (Karstedt's catalyst) followed by shearing and swelling with additional decamethylcyclopentasiloxane to a silicone paste containing 10.2% of the elastomer (Examples 1-5). Zhang further teaches that other types of solvents can swell the silicone elastomer, such as alcohols and fragrances (col. 6, ln. 55 to col. 7, ln. 55). Carrying out the invention is simply a matter of combining the polysiloxane, the alpha, omega-diene, the low molecular weight silicone oil or other solvent, and the catalyst; and mixing these ingredients at room temperature until a gel is formed (col. 7, ln. 56-65). Zhang teaches that silicone elastomers, gels, and pastes are capable of functioning as carriers for pharmaceuticals, biocides, herbicides, pesticides, and other biologically active substances (col. 8, ln. 64-67); as well as being useful as delivery systems for oil and water soluble substances such as vitamins (col. 8, ln. 39-40). Therefore, Zhang clearly teaches compositions comprising an active ingredient, such as pharmaceuticals, combined with a silicone agent and a thickening agent.

The teachings of Sakuta and Schulz et al. are discussed above and incorporated herein by reference.

*Ascertainment of the difference between the prior art and the claims*

*(MPEP 2141.02)*

Zhang does not explicitly disclose the vitamins that can be carried by the invention to comprise vitamin D. However, one of ordinary skill in the art would readily choose vitamin D from the list of vitamins suitable for administration because it is a known vitamin and because Sakuta teaches vitamin D as suitably carried by silicone compositions for cosmetic application (col. 5, ln. 38-43).

Zhang also does not explicitly disclose inclusion of a hydrocarbon-based wax of animal, plant, mineral or synthetic origin. However, Schulz et al. teach incorporating emollients, such as lanolin wax, in their compositions comprising organopolysiloxane elastomer and active agent.

Zhang also does not explicitly disclose the amount of active agent, solvent, silicone elastomer, and agent for promoting the penetration of the active ingredient into the skin, as instantly claimed. However, one of ordinary skill in the art would readily be able to determine the necessary amounts of these components to be suitable for carrying active ingredients for topical administration.

Zhang also does not explicitly disclose incorporation of a hydrocarbon-based compound, such as hydrocarbon-based waxes (i.e., glyceryl behenate or glyceryl dipalmitostearate). However, it was well-known at the time of the instant invention that glyceryl behenate is a suitable emollient/skin conditioning agent for use in cosmetic

formulations. Therefore, one of ordinary skill in the art would have been motivated to use it as an emollient in the topical formulations taught by Zhang.

*Finding of prima facie obviousness*

*Rational and Motivation (MPEP 2142-43)*

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to prepare the compositions according to Zhang wherein the active agent is vitamin D, and the amounts of each component is within the scope of the instant claims. One of ordinary skill in the art at the time of the instant invention would have been able to determine the amounts of each component so that the composition acts as a suitable carrier for topical application.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/  
Primary Examiner, Art Unit 1616